THE UNITED ST TES PATENT AND TRADEMARK OFFICE (Case No. 99-372-F)

PATENT

In re Application of: Welcher al.		
Serial No.: 09/927,850	Before the Examiner: J. Andres	
Filed: August 10, 2001) Group Art Unit: 1646	
For: Interferon-Like Molecule and Uses Thereof		

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

DECLARA' ON PURSUANT TO 37 C.F.R § 1.131

We, Andrew A. Welcher, r iding at 1175 Church Street, Ventura, California; Duanzhi Wen, residing at 3885 Campus Drive, Tousand Oaks, California; and Michael Kelley, residing at 3866

Alta Mesa Drive, Studio City, Cal ornia; hereby declare: We are named co-i ventors on United States Application No. 09/927,850, filed on

- 1. August 10, 2001.
- 2. in the United States by us before. ly 21, 1998 and was then diligently reduced to practice.
- 3.

The invention disc. sed and claimed in the instant patent application was conceived

Accompanying thi Declaration are photocopies of forty-one (41) pages from our laboratory notebook showing con eption of our invention before July 21, 1998. Specifically, the photocopies of our laboratory not sook show that a genomic cloning approach was used to identify the nucleic acid sequence of huma interferon-like polypeptide (see page 34 of laboratory notebook). Three genomic clones were ider fied as containing nucleic acid sequences encoding at least a portion of human interferon-like; lypeptide (i.e., clones 2, 6, and 7; see page 40). The nucleic acid sequences from these clones were solated and then re-cloned into a suitable sequencing vector. One of the three genomic clones was stermined to contain a partial nucleic acid sequence for human interferon-like polypeptide and a other genomic clone (i.e., clone 6) was determined to contain a full-length nucleic acid sequence or human interferon-like polypeptide (see page 62). The amino

sequence.

- 4. The dates on the photocopies. However, the dates
- Also accompanying Research Summary showing tha application was diligently reduced Summary show that experiments encoded by the nucleic acid sequer the protein had been determined, department of Arngen Inc., the assi the Research Summary show tha 10).
- 6. photocopies.
- 7. application or any patent issuing

Dated: June 10, 2004

acid sequence of human interferon ike polypeptide was determined from the latter nucleic acid

iboratory notebook pages have been redacted from the e before July 21, 1998, the date on which U.S. Provisional Application No. 60/093,643 was f d, from which U.S. Application No. 09/487,792 claims the benefit of priority, from which U. Patent No. 6,433,145 issued on August 13, 2002.

this Declaration are photocopies of ten (10) pages from a the invention disclosed and claimed in the instant patent to practice. Specifically, the photocopies of the Research ere performed in order to determine the function of protein e described in paragraph 3 above, and that once the function of Research Summary was prepared and submitted to the legal nee of the instant application. More particularly, photocopies of several versions of the human and rat IFN-L proteins were produced in a mammalian expres on system (see page 7) and that rat IFN-L:Fc fusion protein treatment of several cell lines wa found to cause phosphorylation of cellular proteins (see page

The dates on the Research Summary pages have been redacted from the

We hereby declare urther that all statements made herein by each of us to our own knowledge are true and that all st. ements made on information and belief are believed to be true; and further that these statements v re made with the knowledge that willful false statements and the like so made are punishable by fin or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that su 1 willful false statements may jeopardize the validity of the

Signed: <u>Andrew A. Melcher</u>

Andrew A. Welcher

Duanghi Wen

Michael Kelly

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DATENT

P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

DECLARATION PURSUANT TO 37 C.F.R § 1.131

We, Andrew A. Welcher, residing at 1175 Church Street, Ventura, California; Duanzhi Wen, residing at 3885 Campus Drive, Thousand Oaks, California; and Michael Kelley, residing at 3866 Alta Mesa Drive, Studio City, California; hereby declare:

- 1. We are named co-inventors on United States Application No. 09/927,850, filed on August 10, 2001.
- 2. The invention disclosed and claimed in the instant patent application was conceived in the United States by us before July 21, 1998 and was then diligently reduced to practice.
- 3. Accompanying this Declaration are photocopies of forty-one (41) pages from our laboratory notebook showing conception of our invention before July 21, 1998. Specifically, the photocopies of our laboratory notebook show that a genomic cloning approach was used to identify the nucleic acid sequence of human interferon-like polypeptide (see page 34 of laboratory notebook). Three genomic clones were identified as containing nucleic acid sequences encoding at least a portion of human interferon-like polypeptide (i.e., clones 2, 6, and 7; see page 40). The nucleic acid sequences from these clones were isolated and then re-cloned into a suitable sequencing vector. One of the three genomic clones was determined to contain a partial nucleic acid sequence for human interferon-like polypeptide and another genomic clone (i.e., clone 6) was determined to contain a full-length nucleic acid sequence for human interferon-like polypeptide (see page 62). The amino

acid sequence of human interferon-like polypeptide was determined from the latter nucleic acid sequence.

- 4. The dates on the laboratory notebook pages have been redacted from the photocopies. However, the dates are before July 21, 1998, the date on which U.S. Provisional Application No. 60/093,643 was filed, from which U.S. Application No. 09/487,792 claims the benefit of priority, from which U.S. Patent No. 6,433,145 issued on August 13, 2002.
- Also accompanying this Declaration are photocopies of ten (10) pages from a Research Summary showing that the invention disclosed and claimed in the instant patent application was diligently reduced to practice. Specifically, the photocopies of the Research Summary show that experiments were performed in order to determine the function of protein encoded by the nucleic acid sequence described in paragraph 3 above, and that once the function of the protein had been determined, a Research Summary was prepared and submitted to the legal department of Amgen Inc., the assignee of the instant application. More particularly, photocopies of the Research Summary show that several versions of the human and rat IFN-L proteins were produced in a mammalian expression system (see page 7) and that rat IFN-L:Fc fusion protein treatment of several cell lines was found to cause phosphorylation of cellular proteins (see page 10).
 - 6. The dates on the Research Summary pages have been redacted from the photocopies.
- 7. We hereby declare further that all statements made herein by each of us to our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: <u>June 25, 2004</u>	Signed:	
	Andrew A. Welcher	
	Duanzhi Wen	

Michael Kelly	